EXHIBIT B

Expert Report of Melvin Anhalt, M.D. Regarding the TVT and TVT-O

The following is my general report regarding Ethicon's TVT and TVT-O. All of the opinions expressed in this report are held to a reasonable degree of medical and scientific certainty. My opinions are based on my education, training, knowledge, experience, review of medical literature, discussions with colleagues, attendance at medical meetings, review of case-specific materials including medical records and deposition testimony, and are based on information cited in this report and that which I currently have reviewed and/or have available to me, as set forth in Exhibit A to this report. Inasmuch as I regularly review medical literature, attend and/or participate in medical meetings and consultations with my colleagues, I reserve the right to add to or modify the opinions set forth in this report as appropriate. To the extent I receive additional information relevant to my opinions in this matter, prior to the trial of this case, I reserve the right to modify the opinions set forth below as appropriate.

I. BACKGROUND AND EXPERIENCE

I attended the University of Alabama from 1957-1959 and the Vanderbilt University from 1959-1960. I attended medical school from 1960-1964 at the Medical College of Alabama, and completed my residency in Urology from 1967-

1971 at Baylor University College of Medicine. I remained as a clinical instructor of Urology at Baylor from 1971 through the current time. In 1971, I started my private practice with Memorial Urology Associates in Houston, TX, and continue in that practice today. I am licensed to practice medicine in Texas, and am board-certified by the American Board of Urology. My *curriculum vitae* is attached to this report as Exhibit B, summarizes my education and experience, and includes my publications and presentations as well.

I have been in the private practice of treating women's health issues since 1971. Throughout that time, I have treated women with Urinary Incontinence and Pelvic Organ Prolapse. During my residency, I was trained in the various procedures available to treat such disorders, both surgical and non-surgical. During my career, I have performed the following procedures to repair SUI: anterior urethropexy; Marshall Marchetti Krantz; pubovaginal sling; Stamey procedure; and mid-urethral sling. As medical knowledge advanced, more procedures and treatments became available, which I have likewise performed. Many, if not most, of such treatments evolved as a result of physicians efforts to provide more effective treatments or improved outcomes in their patients, and also, in some instances minimize or avoid certain risks and complications inherent in the existing treatments. For example, the anterior urethropexy and Marshall Marchetti Krantz produced some degree of obstruction and often did not produce lasting

benefit. They also required abdominal incision. The Stamey procedure seemed to work well initially, but by the end of a year, it began to fail. The suburethral sling which I continue to use today has been the safest and most lasting treatment in my experience.

I have observed and participated in the evolution of such treatments and can, therefore attest to that evolution. The availability of synthetic mesh to treat SUI revolutionized surgical options for women with SUI. In the early 2000's , I began using the retropubic TVT (TVT-R) mid-urethral sling marketed by Ethicon. In the mid-2000's I also began using the TVT-O mid-urethral sling in surgery to treat SUI, which provided a different approach for the mesh implantation. Since the TVT line of products began being marketed, they have been my primary surgical repair of choice for treating SUI. I use those products because they are minimally invasive procedures, are done as outpatient surgery, and work well with minimal complications in my experience.

Since the TVT products became available, I have performed or participated in performing over 2000 surgeries utilizing the TVT, and/or TVT-O.

In addition to treating SUI, I have also had significant experience treating pelvic organ prolapse (POP). I have treated POP with both surgical and non-surgical treatments. Non-surgical options have included pelvic floor physical

therapy and pelvic floor exercises, as well as bladder neck bulking procedures. As to surgical options, I have performed the following procedures during my practice in treating POP: open sacrocolpopexy; robotic sacrocolpopexy; prolift repairs; andanterior and posterial repairs.

As with the treatment of SUI, the preferred and available surgical options for treating POP have evolved over time, in many, if not most, instances as a result of physicians' efforts to provide their patients with more effective yet safe treatment options. I have seen and experienced, and thus can testify, to the various revolutionary medical and scientific innovations in this area of medicine which have improved options available to treat women with pelvic floor dysfunction. Moreover, as a result of my 40-plus years of experience, as well as my continuing medical education, review of medical literature, attendance and participation in medical meetings and teaching other physicians, I am familiar with how the surgical treatment of pelvic floor dysfunction is conducted, how physicians obtain information that they utilize in performing various surgical procedures, and the manner in which they apprise themselves of and remain current on advances in medicine relevant to the such treamtent.

Inasmuch as no surgery is without risk, I am familiar with and have on occasion treated complications arising out of the various treatments for pelvic floor

dysfunction. As a result of my continuing review of medical literature, I am aware of the data from studies analyzing not only the efficacy of the various treatments of pelvic floor dysfunction, but also the risks of and complications associated with such procedures. Many of the published medical articles that I have reviewed as part of my practice and efforts to keep abreast of information affecting my patients and to administer appropriate care for my patients, compare the relative efficacy of the various available options for treating pelvic floor dysfunction, and also compare the relative risks/complications associated with those procedures. Accordingly, I can attest, and will if asked, to that data as published and how it affects the opinions I have formed in this case. Many of those articles are included in the materials attached to this report as Exhibit A.

In addition to the surgeries I have performed or assisted in performing myself, I have often been asked to teach or proctor other physicians in performing surgery to treat pelvic organ dysfunction, including POP and SUI. Some of these training sessions have occurred at the request of colleagues who wish to gain more experience and expand their proficiency in performing these procedures. Some training sessions have been conducted as a result of requests from manufacturers of the devices and materials used in performing such procedures in an effort to insure that their products are used by experienced and informed surgeons. I can, therefore, and will, if asked, attest to the training offered by Ethicon in connection

with its synthetic mesh products. The training session I have conducted have included not only didactic lectures, but demonstrations of the surgical techniques with cadavers. I have also trained physicians in the proper use of Ethicon's mesh products during actually surgery on living patients.

II. PRIOR EXPERT TESTIMONY IN THE PAST 4 YEARS

I have testified as a retained expert in the following matters in the past 4 years:

Linda Batiste v. John McNabb, M.D., Johnson & Johnson, and Ethicon Inc., DC-14350 in the District Court of Dallas County, TX.

III. CONSULTING FEES AND TESTIMONIAL HISTORY

My fee for this work is $600 per hour.

IV. MATERIALS REVIEWED IN COMPILING THIS REPORT

In addition to the materials previously referenced in this report which serve as the basis for my opinions in this case, I have also reviewed the IFUs and Surgical Technique Guide for Ethicon's various mesh devices, as well as Surgeon's Resource Monographs, Professional Education slides, DVD's, animations and surgical videos, Patient Brochures, and other professional education materials relating to Ethicon's mesh devices, including the devices specifically at issue in

this case. I am continually reviewing medical literature, and publications from professional societies whose focus is treatment of urological and pelvic floor disorders. As such information becomes available subsequent to the date of this report, I will continue to review that information as part of my continuing medical knowledge, and can and will attest to that information as appropriate, if asked at trial.

V. SUBSTANCE OF OPINIONS FORMED AND TESTIMONY I MAY GIVE IN THIS CASE

A. Urinary Incontinence, Etiology and Treatment

Urinary incontinence is very common in both men and women as we age. Published studies have suggested that 30-40% of older American women are afflicted with some type of urinary incontinence, and many of these will ultimately need surgical repair.

There are different types of urinary incontinence, including urge incontinence and stress urinary incontinence (SUI). Some women suffer from both types of incontinence, a condition referred to as mixed incontinence. Urinary incontinence can have a significant impact on the physical, psychological and social well-being of affected individuals. Uncontrolled leakage and urge incontinence both day and night leads to discomfort, pain, embarrassment, inability to perform every day functions and activities, reduction in sexual desires

and sexual relationships, limitations on personal and business work activities and depression. The impact on the families and careers of women with urinary incontinence may be profound and the resource implications for the health service considerable.

Urge incontinence is the involuntary leakage of urine which occurs when there is a sudden, sometimes overwhelming urgency to urinate. Urgency is often associated with the compelling, sometimes constant need or desire to pass urine that is difficult to pass. The cause of urge incontinence is not well-understood. Urge incontinence can often be treated with medication and behavior modification. Typically, surgery is not an appropriate treatment for urge incontinence. Even with treatment, urge incontinence can and often does progressively worsen with time.

Stress urinary incontinence, or SUI, is an involuntary release of urine that can occur from coughing, sneezing, laughing, or other effort or exertion. SUI occurs when weakened muscles below the urethra do not provide the necessary support for the urethra. SUI can occur as a result of intrinsic sphincter deficiency and hypermobility of the urethra. This leakage can be assessed with diagnostic tools, urodynamic testing, subjective response, physical exam and other means. There are a number of factors that can lead to SUI, which include childbirth, age, estrogen deficiency, tissue disorders, heavy lifting, acute injury in the pelvis,

chronic constipation, obesity, genetics, smoking and potentially other factors. Non-surgical options for treating SUI include behavioral modification. One of the most important behavioral modifications is to stop smoking and for obese women to reduce weight. Even then, though, SUI can and often does worsen. There are no approved medications which effectively treat SUI.

Surgical options for treating SUI include: anterior colporrhaphy, Marshall-Marchetti-Krantz (MMK) , the Burch procedure, sling procedures using autologous, cadaver and graft materials, and mid-urethral sling procedures utilizing synthetic mesh. As stated previously, these surgical options have evolved over time. Fifteen or so years ago when surgery was recommended for patients who had bothersome stress urinary incontinence (SUI), they were offered operations such as suburethral (Kelly) plication, needle urethropexy, open or laparoscopic Burch procedure, and pubovaginal fascial sling procedures. Today, many of these operations have been replaced in practice by retropubic or transobturator midurethral synthetic slings, including the TVT line of products.

Initially, it was thought that in order to adequately treat SUI, the surgical focus needed to be at the bladder neck. With the Burch procedure, the focus changed to the mid-urethra. However, because the Burch procedure was not minimally invasive, had significantly longer recovery times, and was often associated with voiding dysfunction, physicians sought to improve treatment

outcomes, offer minimally invasive surgery, and reduce some of the complications associated with the Burch procedure. They also sought to improve outcomes associated with autologous or other tissue sling procedures, i.e., the primary surgical options if the Burch procedure was not appropriate. These physicians turned their focus to mid-urethral, polypropylene mesh slings with great success. In fact, the use of poloypropolene mid-urethral slings are today considered by most professional organizations responsible, in large part, for establishing recommendations for preferred or standard of care treatment of urogynecological maladies, such as the American Urological Association (AUA), American Urogynecological Society (AUGS), International Urogynecological Association (IUGA), Society for Urodynamics, Female Pelvic Medicine, and Urogentital Reconstruction (SUFU), to name a few, as the gold standard, standard of care and/or first line procedures for surgical treatment of SUI. Inasmuch as I, as well as many, if not most, of my colleagues and other specialists treating SUI rely on the position papers, guidelines, and recommendations of such organizations in treating our patients, I can testify to those recommendations and papers from many of these organizations.

Based on my experience and specialized knowledge of SUI treatment, if asked, I can attest to the history of various procedures to treat SUI, the technical details of such procedures, the morbidity associated with those procedures, length

of hospital stays, complications, safety, effectiveness and why most physicians do not use these procedures any longer as the primary repair for SUI.

As state above, I can and will attest, if asked, to the various published medical, peer-reviewed articles which report on and analyze the relative efficacy and safety of these various procedures. For example, in the Alcalay study, effectiveness of the Burch Colposuspension has been shown to be time dependent, and success rates have been shown to drop after 10 years. Further, pre-op weight greater than 176 pounds has significantly affected cure rates for the Burch. The Kjohede study of long-term success of Burch procedures, showed subjective rates of SUI experienced in 56% of patients after 14 years, and deterioration of the continence rate with time resulting in only 19% reporting no incontinence episodes. Published studies report significant morbidity is associated with the Burch procedure including urinary tract symptoms which in some instances were experienced by as many as 75% of patients; recurrent UTI in 4.6%; de novo detrusor instability in 14.7% of patients; long term voiding difficulty in 22% of patients; and high rates of pelvic organ prolapse associated with the Burch. Many of the published studies have also demonstrated superior efficacy of the mesh procedures over autologous and other tissue slings. See articles listed in Exhibit A.

No surgical option is without risk. The surgical options listed previously for treating SUI, including use of pelvic mesh, include risks of : organ damage, such as

the bladder and other pelvic organs; ureteral injury; damage to bowel, vessels, and nerves in the area of the surgery; risks of anesthesia complications; wound complications and dihiscence, sometimes requiring surgical intervention; infection; granulation tissue or suture granulations;, inflammation; bleeding or hemorrhage and potential need for transfusion; blood clots and hematomas; fistula formation; urinary tract infection and bladder inflammation or cystitis, sometimes recurrent; urinary problems such as voiding dysfunction, de novo detrusor overactivity, de novo urgency, urinary incontinence, urinary retention, urinary frequency, need for self-catheterization, and persistent voiding dysfunction; suture erosion; de novo prolapse ; varying types of pain, sometimes chronic and debilitating, including pelvic pain, vaginal pain, groin pain, and dyspareunia ; adhesions and scarring, and the need for repeat or additional surgery. These risks are well-known to surgeons performing pelvic surgery, are taught during a surgeon's training, and are discussed and acknowledged in published medical articles and texts which surgeons review as part of their training and continuing medical education. Surgeons do not need to be apprised or warned of these risks by pharmaceutical companies such as the manufacturers of pelvic mesh.

The only complication exclusive to pelvic mesh surgery is the risk of mesh exposure, extrusion, and erosion. I have, on occasion, managed such complications, and in my experience, and based upon my review of pertinent

published studies, when these complications do occur, they can often be managed conservatively with observation and/or estrogen cream, or they can be repaired by excising the exposed mesh with minimally invasive procedures. Long-term studies such as those including in Exhibit A, demonstrate that mesh exposure/erosion/extrusion seldom occur with the passage of time. However, in my experience, when such exposure does occur , in most instances the exposure can be managed with minimally invasive treatment.

Based on my training, education and experience in performing these surgeries and managing complications, I can provide testimony as to the relative risks and benefits of such procedures, the relative efficacy of such procedures, potential complications of such procedures, how patients respond to such treatments, and the relative satisfaction patients have with their respective treatments.

B. The TVT Mid-Urethral Slings

Since the 1950s, Prolene sutures made of polypropylene have been used in cardiovascular repairs, hernia repairs and other surgical operations and in millions of patients. Synthetic surgical mesh has been used for hernia repair since the 1940s, and the first polypropylene mesh was developed for hernia repair. In approximately 1974, Ethicon included polypropylene, Prolene mesh in products for

hernia repair. Studies of that large pore, polypropylene mesh, demonstrated its safety and efficacy.

In the 1990s, a group of surgeons lead by a Swedish physician Dr. Ulmsen, began working on an improved way to treat SUI using the integral theory. The procedures at that time for treating SUI caused significant morbidity to patients, long hospital stays, and long-term decreased success rates. Ulmsten's integral theory employed a tension-free placement of mesh under the mid-urethra. He used several different types of meshes (Mersilene, Gore-tex, and others) and determined that the Prolene mesh sold by Ethicon was the most successful. Incorporating Prolene mesh that was 1 centimeter wide and 40 centimeters long. In 1996, Ulmsten published the results of his clinical trial, which included 75 patients whom he followed for two years. 92% of those patients were either cured or significantly improved. There were no tape rejections or defective healing, and no intra-operative or post-operative complications. In the mid-1990s, Ethicon met with Dr. Ulmsten to discuss his procedure and observe his results, and quickly came to realize that his device and procedure would revolutionize the way in which SUI was treated, which it did.

It is my understanding that Ethicon began selling the TVT sling in the United States in 1998. That sling used a retropubic approach (TVT-R). In approximately 2001, a transobturator tape called the Monarch manufactured by a

different company was released to the market. It was a synthetic mid-urethral sling with a transobturator placement which utilized an outside-in approach. In approximately 2002, Ethicon began development of a polypropylene obturator sling utilizing the same mesh as the TVT-R but with an inside-out approach. Studies of that device demonstrated its safety and efficacy, and as a result, the TVT-O became available in the United States in 2003.

The transobturator slings like the TVT-O have become one of the most popular and effective surgical treatments for the female SUI worldwide. Long term or serious complications related to TOT sling passages are rare. For those complications that do exist most are easily treated. With TVT-O, bladder perforations are almost non-existant, and while there can be temporary groin or leg pain in some women , such pain is typically transient resolving with conservative therapy such as analgesics or physical therapay. Most women experience significant improvement of SUI symptoms after sling placement.

The Prolene mesh Ulmsten used in his first studies was the same mesh that Ethicon has used for all of its TVT products, with the exception that a blue dye was added, and some mesh products by 2006 were offered with a laser or mechanical cut. That mesh is utilizes a monofilament, polypropylene , Type 1 macroporous material as defined by NICE and Amid classification. Such mesh has been studied in hundreds of studies and trials, and has been shown to provide appropriate

strength, elasticity, inflammatory response, with resistance to infection and good integration that allows for a successful repair. The TVT mesh is 1379 microns and is therefore a large pore mesh. This pore size provides sufficient room for tissue integration as demonstrated in the literature and in confirmed in my own experience. Long-term studies of the TVT-mesh have demonstrated minimal inflammatory response and almost no tissue reaction. Mesh strength is critical to successful treatment of SUI as the mesh must replace the support where a woman's tissue tone and strength has diminished with age, and the impact of factors such as childbirth, obesity and the other factors mentioned above. Utilizing a larger pore mesh could provide even more elasticity resulting in increased SUI. Moreover, the large pores in the TVT mesh allow the body's immune response to eradicate bacteria resulting in rare instances of infections attributable to the mesh.

Today, there are no mesh slings for treating SUI that employ significantly larger or more elastic meshes than those used in the TVT products. Moreover, I am aware of no data demonstrating significantly improved efficacy or safety with a larger pore mesh. To incorporate such a mesh in a mid-urethral sling with no supporting clinical data, particularly in light of the voluminous data proving the safety and efficacy of polypropylene mesh such as that used in the TVT products, would not be prudent.

C. Clinical Support for TVT products

The TVT products are among the most studied products available to treat SUI. There are more than 80 randomized clinical trials (RCTs) demonstrating the safety and efficacy of TVT and more than 40 such trials relating to the TVT-O. Some of the studies which demonstrate the safety and efficacy of the TVT products include: Some of the publications attesting to this fact include: (Albo ME., N Engl J Med. 2007;356:2143-55); (Richter H, et al. Patient Related Factors Associated with Long-Term Urinary Continence After Burch Colposuspension and Pubovaginal Fascial Sling Surgeries. J Urol. 2012; 188:485-9.);(Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2015 Jul 1;7:CD006375. PMID: 26130017); (Schimpf MO, et al. Society of Gynecologic Surgeons Systematic Review Group. Sling surgery for stress urinary incontinence in women: A systematic review and meta-analysis. Am J Obstet Gynecol. 2014; 211:71.e1-71; AUA 2012 update to SUI Guidelines.https://www.auanet.org/common/pdf/education/clinical-guidance/Incontinence.pdf); (Nilsson CG, et al. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J. 2013; 24:1265-69); Schimpf MO, et al. Society of Gynecologic Surgeons Systematic Review Group. Sling surgery for stress urinary incontinence

in women: A systematic review and meta-analysis. Am J Obstet Gynecol. 2014; 211:71.e1-71.); Ogah J, Cody JD, & Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst. Rev. CD006375 (2009); Rehman H, Bezerra CC, Bruschini H, Cody JD. Traditional suburethral sling operations for urinary incontinence in women. Cochrane Database Syst. Rev. CD001754 (2011); Novara, G., et al., Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol, 2010. 58(2): p. 218-38.); Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2009 Oct 7;(4):CD006375; Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. Neurourol Urodyn. 2011; 30:284-91); Tommaselli GA, et al. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. Int Urogynecol J. 2015; 26:1253-68.); Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2015 Jul 1;7-CD006375. PMID: 26130017); (Novara G, et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions,

pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol. 2010; 58:218–38.);(Nguyen JN, et al. Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. Obstet Gynecol. 2012; 119:539-46.);(Unger CA, et al. Indications and risk factors for midurethral sling revision. Int Urogynecol J. 2015 Jul 2 (e pub)).

DeLaval's original data on the TVT-O demonstrated that the TVT-O is safe and effective. Although Dr. Daoud reported deLeval did not strictly adhere to some of the protocols in the original studies, Ethicon responsibly partnered with Dr. DeLeval to assist him in subsequent trials which showed the same highly successful results. Importantly, 100s of other studies confirmed that the TVT-O is safe and effective and the current gold standard.

In my experience, and based on the many studies referenced and listed in Exhibit A, it is my opinion that the TVT and TVT-O are safe and effective when used in accordance with their intended use and instruction. They are minimally invasive, have low or uncommon complications relative to other procedures to treat SUI, and are the gold standard or standard of care for treating SUI.

I have not observed TVT/TVT-O mesh flaking, degrading, inappropriately or unexpectedly contracting, roping or curling with any clinical effect when the mesh was properly implanted. More importantly, I am aware of no peer-reviewed,

published medical literature or studies demonstrating any clinical significance to any theoretical roping, fraying, degrading, or flaking TVT-related mesh. Similarly, I am aware of no peer-reviewed, published medical literature or studies demonstrating any cytotoxic effect of TVT/TVT-O, polypropylene mesh in humans or that polypropylene mesh causes sarcomas of any type. Polypropylene has been used safely in humans for over five decades. I have seen no reported sarcoma associated with polypropylene or poloypropolene mesh, and have seen no such cytotoxicity in my patients. The FDA has specifically approved and/or cleared polypropylene for numerous uses in the body, including permanent implantation, and given the 50+ years that such materials have been used in humans, if polypropylene, such as that used in TVT-related mesh, were cytotoxic, I would expect there to be such evidence. There is not. Moreover, if the mesh in the TVT/TVT-O products were cytotoxic, I would not expect the professional societies mentioned above, who have conducted comprehensive searches of the available data to find and recommend polypropylene mesh mid-urethral slings as the gold standard for treating SUI.

I am aware of no peer-reviewed, reliable, published data associating polypropylene mesh fibers or particles with an unexpected, increased inflammatory response. Similarly, I am aware of no peer-reviewed, published studies

demonstrating any clinical significance to the laser versus mechanical cut mesh, nor have I seen any such clinical significance in my practice.

The polypropylene mesh incorporated in the TVT products has proven to be the most successful product for surgical treatment of SUI, and no other mesh has demonstrated superior qualities for SUI. Base on my experience and my review of the voluminous literature, as well as the guidelines and publications of the professional societies reference above, in my opinion, there is no safer or more effective, alternative design or product for use in mid-urethral slings to treat SUI than the polypropylene utilized in the TVT mesh.

The published data and publications of the professional societies referenced above demonstrate that TVT line of products have been extensively studied and are safe and effective. Complications are low, morbidity is minimal, and the TVT products are as, or more, efficacious than other surgical procedures for SUI treatment. NICE reported that five devices for the treatment of SUI have high quality efficacy and safety data. Notably, two of the five were TVT and TVT-O.

None of the TVT line of products are unreasonably dangerous. Rather the benefits of the TVT line of products far outweigh the risks. Surgery employing the TVT products is minimally invasive, requires short hospital stays, is highly effective with low rates of complications; it is rare that a SUI repair with a TVT product will result is a serious injury to the patient. Rather many times the

complications that do occur are the result of surgery generally, the patients' own healing factors, and/or factors unrelated to the mesh. Surgical failure and complications often occur in patients who smoke, who are diabetics, who have wound healing issues, and who are prone to adhesions, and as the result of other issues independent of the mesh itself.

D. Instructions for Use and Ethicon's Professional Education Materials

I am familiar with the Instructions for Use (IFU's) and professional education materials provided by Ethicon regarding the TVT products. I have not only read those materials, but I have conducted training of surgeons regarding the TVT procedures. It is my opinion that those materials have at all times been appropriate and adequate to apprise physicians of information relevant to implanting such devices. It is my opinion that Ethicon identified the correct adverse events that can result from the TVT products. Ethicon adequately apprises physicians of the possibility of pain and dyspareunia associated with the TVT devices. Further, all pelvic/urologic surgeons know that pain or dyspareunia can occur with any SUI surgery as this is trained in medical school, residencies, fellowships and by Ethicon in professional education. Ethicon further warns of transient leg pain that is consistent with what occurs with the TVT-O. When there is long-term pain, it can occur from damage to nerves or from erosion which is warned of in the IFU.

The professional education program offered by Ethicon for its TVTproducts, including training materials, types of training available, compensation spent on professional education, selection criteria of trainees and other facets of professional education are exceptional. Ethicon is not required to provide professional education, but chooses to do so in order to facilitate patient safety. The professional education program of Ethicon is multifaceted in order to provide physicians with multiple training opportunities for the safe and effective use of TVT products. Ethicon specifically provides a didactic portion, cadaver labs, preceptorship (direct observation in the operating room where surgeons will be invited into the OR and watch an experienced surgeon perform the TVT™ procedure) and proctorships (preceptor for Ethicon would be a guest in another surgeon's operating room and directly observe them performing the TVT™). Ethicon encourages physicians to undergo this training and will provide as many training opportunities as the surgeon desires to undergo. Further, there are advanced user courses that Ethicon provides as well. The professional education provides an overview of the procedure (including mesh tensioning, placement, tension-free placement, etc), clinical data, complications, complication management and many other aspects. Once a trainee undergoes this training the physicians providing the training make themselves available for further questions regarding such training as needed. The professional education program does not

certify physicians that they can perform the procedure, it simply a certificate of completion.

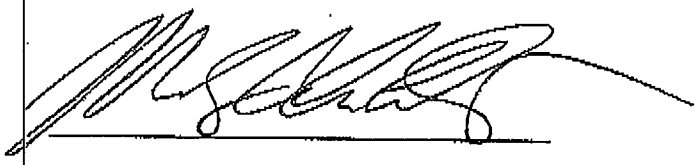
Ethicon's Profession Education Program is not a credentialing process. Ethicon provides physicians attending the sessions a certificate noting that a surgeon did attend their course on a particular product like the TVT. This certificate by no means verifies that the physician is proficient at performing the procedure.

The certificate from the program simply documents the surgeon's attendance at an Ethicon Professional Education Event. It shows that the physician made an attempt to be educated on the procedure and Ethicon's efforts to provide exposure to their products. The actual credentialing should always occur at the hospital to determine if the physician is qualified to perform a procedure. Ethicon specifically warns that physicians should be familiar with SUI surgeries and appropriately trained. Most importantly it is up to the individual physicians to decide which procedures the surgeon is capable of performing. It is further the physician's responsibility to know the pelvic anatomy, understand biomaterials and properly select patients for the procedure.

E. TVT PATIENT BROCHURE

The patient brochure provided by Ethicon to physicians is offered to facilitate a conversation with the patient and the physician. The patient brochure is not to be the sole piece of information that a patient is provided or uses in making treatment decisions. Rather, what is most critical is the discussion between the patient and the physician as to treatment options, potential complications relevant to the individual patient, based on the peculiar characteristics of that patient, and the physician's experience and success rates in performing the procedure. The brochure is not only adequate, but is an excellent tool to supplement the discussion with the physician. It appropriately identifies other forms of treatment, and the "what are the risks" section accurately and appropriately identifies the potential complications with mesh.

I hold the opinions expressed in this report to a reasonable degree of medical certainty. I reserve the right to modify or amend this report before trial as more information becomes available relevant to my opinions.



Melvyn Anhalt, M.D.